# **REMARKS**

Claims 135-170 are currently pending.

#### Rejection of Claims 135-138 and 153-156 Under 35 U.S.C. §§ 102(e) and 103(a)

In the September 10, 2004 Office Action, the Examiner rejected claims 135-138 and 153-156 under 35 U.S.C. §§ 102(e) and 103(a) as being allegedly unpatentable over U.S. Patent No. 6,517,863 (hereinafter "LaTorre"). With respect to the § 102(e) rejection, the Examiner asserted that LaTorre discloses compositions and methods for treating nails and adjacent tissues comprising particles of bioactive glass that have anti-microbial properties, alone or in combination with therapeutic agents, hydrophilic polymers and other additional agents. The Examiner also asserted that LaTorre discloses bioactive glass compositions that can be prepared in several ways to provide melt-derived glass, sol-gel derived glass, and sintered glass particles. With respect to the § 103(a) rejection, the Examiner asserted that LaTorre discloses that bioactive glass can include additional components such as antibiotics, antivirals and other additives. In addition, the Examiner asserted that LaTorre discloses that bioactive glass also has anti-microbial properties (pointing to Col. 2, lines 62-66).

In response, applicants respectfully traverse the Examiner's rejection under 35 U.S.C. §

102. Applicants maintain that claims 135-138 and 153-156 are not anticipated by LaTorre.

Applicants point out that claims 135 and 153 are the only presently pending independent claims.

Claim 135 recites:

A cosmetic composition comprising bioactive glass and a substantially anhydrous cosmetic formulation with the proviso that said bioactive glass does not comprise ions of silver, copper or zinc. Claim 153 recites:

A method of making a cosmetic composition comprising combining bioactive glass with a substantially anhydrous cosmetic formulation with the proviso that said bioactive glass does not comprise ions of silver, copper or zinc.

Applicants point out that LaTorre does not disclose, teach or suggest the cosmetic compositions or methods of making cosmetic compositions according to the presently claimed invention. In sharp contrast to LaTorre, the present invention (1) works using substantially anhydrous cosmetic formulations; (2) does not require the presence of additional anti-microbial agents; and (3) provides a long duration of effectiveness.

# "Substantially Anhydrous"

As specifically recited in independent claims 135 and 153, the presently pending claims require the presence of a substantially anhydrous cosmetic formulation. Since LaTorre does not disclose a cosmetic composition comprising a substantially anhydrous cosmetic formulation,

LaTorre cannot anticipate the presently pending claims.

More particularly, LaTorre stresses the criticality of using aqueous solutions or hydrophilic ("water-loving") polymers for the LaTorre invention to work. For instance, LaTorre discloses using either an aqueous solution or, alternatively, a gel based formulation (which uses a hydrophilic polymer) to create a layer of hydroxyapatite or other calcium phosphate mineral on the nail. (Col. 2, lines 48-61.) LaTorre further states that "[a]n effective nail-enhancing amount of bioactive glass is defined as an amount capable of providing the nail surface with at least a thin coating of hydroxyapatite." (Col. 3, lines 30-33.) LaTorre also states that the theory behind the invention is the "adsorption of hydronium ions <u>from a solution</u> and a release of sodium and/or calcium ions..." (Emphasis supplied.) (Col. 3, lines 38-40.)

LaTorre confirms beyond doubt the criticality (for the LaTorre invention) of aqueous or hydrophilic-based compositions when describing formulations which include bioactive glass. In doing so LaTorre states.

The bioactive glass or extract of bioactive glass <u>may be</u> administered to the nail in a topical formulation, such as in the form of a suspension, lotion, cream (water-in-oil emulsion) or gel, provided that the formulation includes a sufficient amount of water such that the ions can be formed and allowed to react with the nail to form the hydroxyapatite layer. [Emphasis supplied.] [Col. 4, line 62 - Col. 5, line 3.]

And finally, Example 1 in LaTorre (the only example in which an arguably cosmetic formulation comprising bioactive glass is described), used an equal volume of bioactive glass and water to form a paste. (See Col. 6, lines 45-62.) No example describes a substantially anhydrous cosmetic formulation or method.

Accordingly, since it is abundantly clear from the above that LaTorre does not disclose substantially anhydrous cosmetic compositions and methods, LaTorre cannot anticipate the currently pending claims. Moreover, LaTorre cannot render obvious claims 135-138 and 153-156 for the same reason since the "substantially anhydrous" element is not disclosed. For the sake of completeness, however, applicants provide additional bases for the non-obviousness of claims 135-138 and 153-156.

"Does Not Require The Presence Of Additional Anti-Microbial Agents"

The LaTorre reference not only stresses the criticality of water for the LaTorre invention to work, but also concedes the need for additional anti-microbial additives to provide a significant anti-microbial effect. In contrast, the presently claimed invention provides significant anti-microbial properties without the use of water or anti-microbial additives.

First, it should be noted that LaTorre is not directed to the use of compositions comprising bioactive glass having anti-microbial effects, but rather to the formation of a hydroxyapatite layer on fingernail (and presumably toenail) surfaces. LaTorre mentions tangentially, and only once, that bioactive glass also has antimicrobial properties, but taken in context it is clear that LaTorre does not consider those properties to be significant. More specifically, LaTorre states that:

...the compositions can include additional components, such as antibiotics, antivirals, antifungal agents...and other cosmetically useful additives. Bioactive glass also has antimicrobial properties. [Col. 2, lines 62-67.]

Accordingly, LaTorre does not suggest that any anti-microbial property of bioactive glass is sufficient to impart preservative qualities to cosmetic formulations themselves. At most LaTorre suggests that the formulations disclosed therein, upon application to the nailbed or surrounding tissue, might have some beneficial local effect in combination with the other anti-microbials additives listed in the reference. In addition, as discussed above, LaTorre stresses the criticality of water for the proper functioning of all of the disclosed formulations. LaTorre does not disclose, teach or suggest any anti-microbial effect of cosmetic compositions comprising bioactive glass and a substantially anhydrous cosmetic formulation or methods of making same.

Accordingly, for this additional reason, applicants maintain that LaTorre does not render obvious claims 135-138 or 153-156.

# "Long Duration Of Effectiveness"

LaTorre also does not disclose stable cosmetic compositions (or methods of making such compositions) comprising bioactive glass and a substantially anhydrous cosmetic formulation.

Rather, LaTorre discloses that:

It is preferable that the glass not be significantly prereacted prior to application to the nails. This can be achieved, for example, by mixing the bioactive glass and water to form the compositions and applying the composition to the nails immediately after mixing. [Emphasis supplied.] [Col. 5, lines 52-56.]

In contrast, the presently claimed invention provides stable compositions (and methods of making same) comprising bioactive glass and a substantially anhydrous cosmetic formulation. Such compositions have an extended duration of effect and, unlike LaTorre, do not need to be used immediately upon combination. For this additional reason, applicants maintain that LaTorre does not render obvious claims 135-138 or 153-156.

For all of the foregoing reasons, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 135-138 and 153-156 under 35 U.S.C. §§ 102(e) and 103(a) over LaTorre.

# Rejection of Claims 139-152 and 157-170 Under 35 U.S.C. § 103(a)

In the September 10, 2004 Office Action, the Examiner rejected claims 139-152 and 157-170 under 35 U.S.C. § 103(a) as being allegedly unpatentable over LaTorre in view of U.S. Patent No. 6,224,888 (hereinafter "Vatter"). The Examiner acknowledged that LaTorre did not disclose cosmetic additives such as jojoba oil, glycerin, parabens and pigments. The Examiner asserted, however, that would have been obvious to one of ordinary skill in the cosmetic art to include additives, such as oils, waxes, pigments and the like.

In response, applicants respectfully traverse the Examiner's rejection under § 35 U.S.C. 103(a). Applicants maintain that claims 139-152 and 157-170 are not rendered obvious by LaTorre in view of Vatter.

As an initial matter, applicants point out that the Examiner has not provided any explanation for how or why a person of ordinary skill in the art would be motivated to combine

Attorney Docket No.: 99866/9

Customer No. 31013

LaTorre with Vatter to arrive at the presently claimed invention. But even if these references

were combined, the Examiner relies on Vatter simply for its recitation of cosmetic excipients.

Vatter does not cure (and the Examiner has not stated that Vatter cures) the deficiencies of

LaTorre discussed in detail above.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw

the rejection of claims 139-152 and 157-170 under 35 U.S.C. § 103(a) over LaTorre in view of

Vatter.

Conclusion

In view of the foregoing, applicants respectfully request that the Examiner reconsider and

withdraw the rejections set forth in the September 10, 2004 Office Action and allow the

presently pending claims, namely claims 135-170.

No fee, other than the fee for a three-month extension of time, is believed to be necessary

in connection with the filing of this Communication. However, if any additional fee is

necessary, applicants hereby authorize such fee to be charged to Deposit Account No. 50-0540.

If a telephone interview would be of assistance in advancing the prosecution of this

application, applicants' undersigned attorney encourages the Examiner to telephone him at the

number provided below.

Respectfully submitted,

Dated: March 7, 2005

Robert E. Alderson, Jr.

Registration No. 44,500

Attorney for Applicants

KRAMER LEVIN NAFTALIS & FRANKEL LLP

919 Third Avenue

New York, New York 10022

(212) 715-7697

- 7 -